



**Letter to the Editor: Re: Comparison of Periodontal Parameters and Self-Perceived Oral Symptoms among Cigarette-Smokers, Individuals Vaping Electronic-Cigarettes and Never-Smokers: A Pilot Study.**

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To the Editor,

**RE: Javed F, Abduljabbar T, Vohra F, Malmstrom H, Rahman I, Romanos GE. Comparison of Periodontal Parameters and Self-Perceived Oral Symptoms among Cigarette-Smokers, Individuals Vaping Electronic-Cigarettes and Never-Smokers: A Pilot Study. J Periodontol. 2017;1-9.**

We read with interest the pilot study by Javed et al (1) comparing periodontal parameters in cigarette smokers, electronic cigarette (e-cigarette) users and never-smokers. The role of novel nicotine devices (such as e-cigarettes) in smoking cessation and any potential oral health effects are very important topics that require further research. However, the purpose of this letter is to raise methodological and statistical concerns with this study, particularly the inappropriate use of its description as a 'pilot study'.

Pilot studies, also known as feasibility studies, are an important research design and ensure that future definitive studies are well designed, appropriately powered and deliverable. The purpose of pilot studies is to assess feasibility, which is fundamentally different to definitive studies which will have aims such as effectiveness or efficacy. Pilot studies should focus on descriptive statistics (with confidence intervals) rather than formal hypothesis testing.

Within the medical literature, it has been identified that pilot studies are often poorly conducted and inadequately reported. Lancaster et al(2) summarised these concerns: 'pilot studies play an important role in health research, but they can be misused, mistreated and misrepresented'. Subsequently, the CONSORT (Consolidating Standards of Reporting Trials) group developed an extension to their CONSORT 2010 statement to cover pilot and feasibility trials (3). Although this is primarily directed at randomised controlled trial (RCT) designs, the principles are transferrable to other research designs.

Javed et al (1) describe their study as a pilot study in the title but confusingly the rest of the paper reads like a definitive study. There is no mention of pilot or feasibility objectives, no mention of the future definitive study nor how this pilot will inform that study.

We would also like to highlight concerns with the 'power analysis' presented in this study. Often one of the major reasons for conducting a pilot study is to inform a sample size calculation for a definitive study by estimating the variability of the primary outcome measure. Recommendations suggest that to obtain a robust estimate, outcome data for approximately 30-35 participants per arm are required (2, 4). Javed et al (1) do not follow this approach and instead describe a more formal sample size calculation as for a definitive study. Unfortunately the information provided for their sample size calculation is inadequate and is not reproducible (reproducibility is an important requirement for any research report). For example, the estimated standard deviation of the outcome measure is not provided, an essential parameter for this calculation (perhaps because this it is not yet known in this field and establishing this should be one of the aims of this pilot study). Two target differences are proposed, 0.5 mm for MBL and 1 mm for PD, with no justification of why these differences are deemed clinically meaningful. Nor is it clear whether the power calculation takes in to account the planned multiple comparisons.

The design of this study is not clearly defined within the paper. It appears that it is a cross-sectional observational study with a volunteer sample. A key weakness of this design is that it is not possible to rule out confounding; in other words, observed differences in the outcomes of interest between the three groups may be attributable to differences in demographic composition or other prognostic factors. There is no evidence of adjustment for confounders.

No random sampling was performed, an essential requirement for statistical tests to be valid.

In summary, pilot studies play an important role in health research but they should not be used as an excuse for poor design and inadequate sample sizes. We call for researchers and journal editors to ensure the highest levels of research rigor are followed and suggest the CONSORT 2010 (pilot and feasibility trial) checklist (3) is utilised where appropriate.

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Conflict of interest: Nil.

#### References:

1. Javed F, Abduljabbar T, Vohra F, Malmstrom H, Rahman I, Romanos GE. Comparison of Periodontal Parameters and Self-Perceived Oral Symptoms among Cigarette-Smokers, Individuals Vaping Electronic-Cigarettes and Never-Smokers: A Pilot Study. *J Periodontol*. 2017;1-9.
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